UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: Suits Naming the Tennessee Clinic Defendants	

NOTICE OF FILING
SUBPOENA TO THE MASSACHUSETTS BOARD OF PHARMACY

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants") give notice to the Court and to all parties, pursuant to Federal Rule of Civil Procedure 45(a)(4), of the issuance of a subpoena to the Massachusetts Board of Registration in Pharmacy ("Mass. BoP"). The subpoena commands the production of documents and requires the deposition testimony of a Mass. BoP representative pursuant to Federal Rule of Civil Procedure 30(b)(6).[1] The subpoena was emailed to the Mass. BoP and to directly involved counsel today, with a copy put in the mail after the service by email. This Notice is filed in the main docket to ensure each party has notice of the subpoena.

[1] The subpoena to the Mass. BoP is attached as Exhibit 1 to this Notice.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
315 Deaderick Street, Suite
Nashville, TN 37238
Ph: (615) 254-0400
Fax: (615) 254-0459
chris@gideoncooper.com

Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 18th day of March, 2015.

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT 1

Subpoena to the Mass. BoP

AO 88A (Rev. 02/14) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation *Plaintiff*

v.

Tennessee Clinic Defendants

Defendant

Civil Action No. 1:13-md-02419

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Massachusetts Board of Registration in Pharmacy

(Name of person to whom this subpoena is directed)

☑ *Testimony:* **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Place:	Date and Time:
Massachusetts Board of Pharmacy 239 Causeway Street, 5th Floor, Suite 500 Boston, MA 02114	05/06/2015 9:00 am EDT

The deposition will be recorded by this method: Stenographical means and by video

☑ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material: See attached Duces Tecum, Exhibit 1 to Notice of 30(b)(6) Deposition

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 03/18/2015

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Tennessee Clinic Defendants, who issues or requests this subpoena, are:

Chris J. Tardio; 315 Deaderick St., Suite 1100, Nashville, TN 37238; chris@gideoncooper.com; (615) 254-0400

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	
	)	**MDL No. 2419**
	)	**Dkt. No 1:13-md-2419 (RWZ)**
THIS DOCUMENT RELATES TO:	)	
All cases	)	

Notice of 30(b)(6) Deposition

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Federal Rule of Civil Procedure 30(b)(6), come now and give notice that the oral and videotaped deposition of the Massachusetts Board of Registration in Pharmacy ("Mass. BoP"), as an organization, will be taken on the topics detailed below. The Mass. BoP shall identify the person(s) who will speak on its behalf on each topic at least seven (7) days before the deposition(s).

The deposition will be taken on May 6, 2015, beginning at 9:00 a.m. (EDT) and continuing until completed. The deposition will take place at Massachusetts Board of Pharmacy, 239 Causeway Street, 5th Floor, Suite 500, Boston, MA 02114. The deposition will be recorded by stenographical means and by video.

Pursuant to Federal Rule of Civil Procedure 30(b)(6), the Mass. BoP's designee(s) shall be prepared to testify regarding the following subjects:

Mass. BoP's authority to investigate, inspect, regulate, and take action against NECC

1. The Mass. BoP's authority under Massachusetts law to investigate, inspect, regulate, and take enforcement action against New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC") during the time of NECC's operation.

2. The Mass. BoP's internal policies (written or otherwise), procedures (written or otherwise), and training of staff from 2002 to the time of the meningitis outbreak on the (1) inspection of compounding pharmacies, (2) when regulatory action was appropriate against compounding pharmacies, and (3) distinguishing between traditional pharmacies, traditional compounding, large-scale compounding similar to drug manufacturing (now called "outsourcing facilities"), and conventional drug manufacturers.

3. Generally, the Mass. BoP's authority to take enforcement actions against pharmacies, and how that authority can be exercised (*i.e.*, generally, the differences between the types of enforcement actions available to the Mass. BoP, *e.g.*, private censures, warning letters, seizures, injunctions, criminal actions, civil penalties, *etc.*).

Mass. BoP's investigation, inspections, regulation, and actions related to NECC

4. NECC's 1998 Application for Registration to Manage and Operate a New Community Pharmacy.

5. All complaints about NECC known by the Mass. BoP prior to the meningitis outbreak and the Mass. BoP's response to these complaints, including the internal decision-making regarding whether and how to investigate, inspect, and take action against NECC. The complaints and related investigations, inspections, and actions that the witness should be prepared to testify about include, but are not limited to:

a. 1999 private, non-disciplinary letter to NECC regarding providing blank prescription forms to physicians

b. Complaint from the Idaho Board of Pharmacy to Mass. BoP in 2001 notifying the Mass. BoP that NECC continued to use blank prescription forms

c. Complaints about NECC that the Mass. BoP received from the Nevada Board of Pharmacy in April 2002

d. The joint investigations of NECC conducted by the Mass. BoP and the FDA in April 2002 and from October 2002-February 2003, and the results of the investigations

e. The formal complaint filed by the Mass. BoP against NECC in February 2003

f. The meeting in February 2003 between the FDA and Mass. BoP and the plan of action developed regarding addressing the ongoing issues with NECC

g. February 2004 and September 2004 inspections of NECC by the Mass. BoP and the FDA

h. The three private censures of NECC in 2004 by the Mass. BoP

i. The 2006 Consent Agreement between NECC and the Mass. BoP

j. The 2006 assessment reports by Pharmacy Support, Inc. required by the 2006 Consent Agreement with NECC

k. The warning letter sent to NECC in 2006 by the FDA arising from the 2004 joint inspection by the FDA and Mass. BoP

l. The indication in the 2006 Warning Letter that NECC was not using patient-specific prescriptions for compounded medications

m. The 2011 and 2012 reports from the Colorado Board of Pharmacy to the Mass. BoP regarding NECC's actions in Colorado and the Mass. BoP's actions (or lack of action) against NECC based on these reports

n. The inspection of NECC by the Mass. BoP on May 24, 2011.

6. Any and all complaints about NECC received by the Mass. BoP or actions by the Mass. BoP in response to complaints about NECC not specifically referenced in Number 5(a)-(n).

7. Any and all correspondence and communications between the Mass. BoP and NECC (including its owners, agents, employees, and representatives) not specifically referenced in Number 5(a)-(n).

8. Any and all correspondence and communications between the Mass. BoP and the FDA or other state pharmacy boards related to NECC not referenced in Number 5(a)-(n).

Cooperation with the FDA

9. Whether, based on information learned by the Mass. BoP about NECC prior to the meningitis outbreak, the Mass. BoP believed that NECC was operating like a conventional drug manufacturer (or, at a minimum, operating on a scale not akin to a traditional pharmacy compounder), subjecting it to FDA regulatory authority, or whether the Mass. BoP believed NECC remained within the regulatory authority of the Mass. BoP.

10. Information about NECC that the FDA shared with the Mass. BoP prior to the meningitis outbreak and any enforcement action the FDA suggested the Mass. BoP should take against NECC's state license.

11. The Mass. BoP's cooperation with the FDA in investigating, inspecting, and taking action against NECC prior to the meningitis outbreak.

12. The Mass. BoP's public statements since the outbreak regarding (1) whether it should have but failed to take disciplinary actions against NECC at the junctures described in 5(a)-(n) above (or at any other times); (2) whether these failures constituted a negligent failure to exercise its regulatory duty; and (3) whether these failures caused or contributed to the meningitis outbreak.

The information known by the Mass. BoP about NECC and whether/how it was made public

13. What, if any, of the information known by the Mass. BoP about NECC's failure to follow federal law, state law, or industry standards for production of drugs was made publicly available prior to the meningitis outbreak and the steps necessary for potential customers of NECC to obtain the information from the Mass. BoP.

14. What information about NECC the Mass. BoP would have provided to someone requesting information about NECC in 2011 or 2012 prior to the meningitis outbreak.

15. Whether the Mass. BoP issued any alerts to health care providers or other government agencies prior to the meningitis outbreaks related to NECC (*e.g.*, that it was unsafe to purchase from NECC; that it was unsafe to purchase certain drugs from NECC; that NECC was operating in violation of federal or state law; *etc.*).

Mass. BoP's investigation and inspection of, and action against NECC, following the meningitis outbreak

16. The findings of the Mass. BoP based on its investigation and inspection of NECC following the meningitis outbreak as captured in its October 23, 2012, report, including (but not limited to):

a. The Mass. BoP's finding that NECC distributed recalled lots of MPA before it received sterility testing results

b. Observation of visible particulate matter in several recalled sealed vials of MPA from Lot 08102012@51

c. NECC's failure to follow proper USP 797 autoclaving sterilization procedure

d. NECC's cleanrooms used to compound drugs were not appropriately sealed

e. NECC's cleanrooms used to compound drugs were not thoroughly cleaned pursuant to USP 797 or NECC's standard operating procedures

f. Whether NECC failed to comply with other USP standards.

Ameridose and Alaunus Pharmaceuticals

17. The findings of the Mass. BoP's inspections and investigations of Ameridose and Alaunus Pharmaceuticals ("sister" companies owned and operated by the same owners and operators of NECC), including, but not limited to:

a. Whether the Mass. BoP had knowledge of 2009 complaints from Ameridose employee(s) that the owners and operators of Ameridose (the same owners and operators as NECC) directed outside testing companies to change results, forged documents, and "doctored" findings

b. Whether the Mass. BoP had knowledge of July 2010 complaints by a pharmacist at Ameridose that Ameridose was ignoring its quality assurance program

c. Whether the Mass. BoP had knowledge of August 2010 complaints by a pharmacist at Ameridose that Ameridose had its sales team labeling drugs in a clean room, that a clean room had tested positive for mold growth, and that Ameridose was manipulating its environmental testing

d. Whether the Mass. BoP had knowledge of February 2011 complaints about Ameridose not safely labeling its compounded sodium chloride

e. Whether the Mass. BoP had knowledge of August 2011 complaints by an Ameridose employee that Ameridose's management instructed its staff to ship packages even if they were dropped on the floor in a dirty room

f. Whether the Mass. BoP had knowledge at any time of complaints or allegations that Ameridose was compounding or manufacturing drugs for NECC because NECC did not have the capacity to fill large orders.

Documents

18. The documents that the witness(es) is requested to produce in the *duces tecum* attached as Exhibit 1 to this Notice.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
315 Deaderick Street, Suite
Nashville, TN 37238
Ph: (615) 254-0400
Fax: (615) 254-0459
chris@gideoncooper.com

Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 18th day of March, 2015.

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT 1

Duces Tecum to Notice

EXHIBIT 1 – *DUCES TECUM*

Instruction: To the extent these documents can be provided electronically by posting to a web-based repository or provided on CD or flash drive, that is preferable.

1. The witness's most current professional resume or *curriculum vitae.*

2. Any and all *public* documents related to NECC (documents the Mass. BoP made available to the general public) in the possession or control of Mass. BoP *prior to the meningitis outbreak.*

3. Any and all *non-public* documents related to NECC (documents the Mass. BoP did *not* make available to the general public) in the possession or control of Mass. BoP *prior to the meningitis outbreak.*

4. Any and all documents related to NECC in the possession or control of the Mass. BoP since the meningitis outbreak.

   Further instructions on requests 2, 3, and 4:

   > *Requests 2 and 3 seek production of the pre-outbreak Mass. BoP "file" for NECC available to the public (request 2) and separate production of the pre-outbreak internal Mass. BoP "file" for NECC not available to the general public (request 3). Request 4 ensures that all NECC-related documents, including those related to the outbreak through the present, are produced.*
   >
   > *To the extent these documents have, since the outbreak, been posted on a website for public access, please identify the specific website where the Tennessee Clinic Defendants can access the entirety of the documents and determine what was publicly available prior to the outbreak versus what was part of the Mass. BoP's non-public file.*
   >
   > *If some documents are withheld on assertion of privilege or for any other reason, please identify the documents with reasonable particularity and the reason the documents have been withheld.*

5. All treatises, scholarly journals, professional studies, professional literature, or similar documents the witness intends to rely upon in giving testimony responsive to this Notice.

6. Any and all documents, not privileged, reviewed or relied on by the witness in preparation for giving testimony pursuant to the Notice.

7. Mass. BoP's internal policies, procedures, or training materials in place from 2002 to the time of the meningitis outbreak related to the investigation, inspection, and regulation of, and enforcement action against, (1) compounding pharmacies, generally, and (2) large-scale compounding pharmacies (compounding pharmacies operating beyond the definition of traditional compounding and acting more similar to conventional drug manufacturers).

8. Any documents provided by NECC to the Mass. BoP at any time as part of the Mass. BoP's investigations of NECC.

9. Any documents provided by the FDA to the Mass. BoP related to investigations of NECC.